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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,121	10/20/2003	William Kopaciewicz	MCA-617	2908
42754	7590	01/25/2006	EXAMINER	
NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581			HANDY, DWAYNE K	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 01/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,121

Applicant(s)

KOPACIEWICZ ET AL.

Examiner

Dwayne K Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/17/03 & 1/26/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to a method of forming a structure in a housing, classified in class 436, subclass 165.
 - II. Claims 7-16 and 18, drawn to a sample preparation device, classified in class 422, subclass 101.
 - III. Claim 17, drawn to a method of purifying a sample, classified in class 436, subclass 177.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as storing and/or reacting compounds in the housing.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another

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and materially different process such as manually inserting a precipitated polymer into the housing.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Mr. Kevin Lemack on 12/06/04 a provisional election was made with traverse to prosecute the invention of the method of forming a structure in a housing, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,635,201 ('201).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-18 of the patent recite a method of casting a composite structure comprised of the steps of forming a polymer solution, adding porous particles to the solution, introducing the solution into a housing, and then causing the polymer to form a porous polymer matrix. These steps fully encompass the steps recited in the instant claims 1-3.

7. Claims 1-3 and 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,830,717 ('717). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-12 of the patent recite a method of casting a composite

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structure in a housing comprised of the steps of forming a casting solution of polymer and adding porous particles, introducing the solution into a housing, and then causing the polymer to form a porous polymer matrix. These steps fully encompass the steps recited in the instant claims 1-3.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kopaciewicz et al. (6,048,457). Kopaciewicz teaches a method for casting-in-place composite structures which are useful as separation media. The Examiner directs applicant to the passages from columns 5 and 6 copied below:

(5) In accordance with the present invention, the structures of the present invention can be formed by a polymer phase inversion process, air casting (evaporation) and thermal inversion. For those systems with minimal or no adhesion, the formed structures can be separately prepared and inserted into the appropriate housing and held in place by mechanical means. In the preferred method, the formed structures are cast in situ in the desired housing. This results in the ability to include large amounts of media in the polymer matrix while still maintaining a three-dimensional porous structure. The membrane substructure serves as a support network enmeshing the particles, thus eliminating the need for frits or plugs, thereby minimizing or even eliminating dead volume (the adsorptivity of the membrane may or may not participate in the adsorption process). However, porous frits plugs could be added if desired. Preferably the membranes or composite structures formed have an aspect ratio (average diameter to average thickness) of less than about 20, more preferably less than about 10, especially less than 1. For example, for adsorptive pipette tips, aspect ratios of two or less, more preferably less than 1 are preferred, especially between about 0.005-0.5. An aspect ratio within this range provides for suitable residence times of the sample in the composite structure during operation.

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(6) In the polymer phase inversion process, the solvent for the polymer must be miscible with the quench or inversion phase. For example, N-methyl-pyrrolidone is a suitable solvent for polysulfones, polyethersulfones and polystyrene. In the latter case, polystyrene pellets can be dissolved in N-methyl-pyrrolidone and cast-in-place. The resulting structure shows good adhesion to the walls of a polyolefin-based housing, and has adsorption characteristics similar to polysulfone. Dimethylsulfoxide (DMSO), dimethylform-amide, butyrolactone, and sulfalane are also suitable solvents. N,N-dimethylacetamide (DMAC) is a suitable solvent for PVDF. Water is the preferred precipitant. The polymer phase inversion process generally results in an expansion of the structure to about two to three times its casting solution volume in the housing.

(7) In the air casting process, a volatile solvent for the polymer binder is used. For example, in the case of cellulose acetate, acetone is a suitable volatile solvent. Air casting generally results in a structure which is smaller than the casting solution volume. With this method, particles in the filled structures should be at least about 30 μ m. to allow flow through the interstitial spaces after shrinkage without having to apply higher driving force.

(8) The upper limit of particle amounts is dictated by casting solution viscosity. Depending on particle type, up to 40% (w/w) of particles can be added to the polymer without resulting in a casting solution too viscous to draw into the housing. Higher particle loadings may be achieved using higher temperature. Suitable particle sizes include particles in the range of from about 100 nanometers to about 100 microns in average diameter with or without porosity.

(9) Suitable housing materials are not particularly limited, and include plastics (such as polyethylene and polypropylene), glass and stainless steel. Polyolefins, and particularly polypropylene, are preferred housing materials in view of the chemical adhesion that is created with the composite structure when the composite containing polysulfone, and in particular UDEL P3500 and P1700 polysulfones available from Amoco, is cast-in-place therein. FIG. 16B illustrates such adhesion with a polypropylene pipette tip housing having a cast-in-place membrane therein prepared with spherical silica gel and polysulfone.

(10) Suitable housing configurations are also not particularly limited, and include pipette tips, wells, multi-well arrays, plastic and glass cavities, sample preparation devices such as the MICROCON.RTM. microconcentrator, commercially available from Millipore Corporation, etc. The preferred housing configuration is substantially cylindrical, as the flow vectors during operation are substantially straight, similar to chromatography, thereby minimizing or avoiding dilutional washing that might occur with non-cylindrical configurations. Although housings with volumes between about 0.1 μ l and about 5 mls. can be used for casting-in-place, volumes less than about 100 μ l are preferred, with volumes of from about 0.1-50 μ l, preferably from about 0.2-20 μ l, are especially preferred. Pipette tip geometries having volumes as small as about 5 microliters can be used. When chemical adhesion of the composite structure to the housing walls is desired but is insignificant or non-existent, mechanical means can be used to maintain the composite structure in the housing, such as crimping, press fitting, heat shrinking the housing or a portion thereof, plasma treating the housing or a portion thereof, or chemically treating, such as etching, the housing or a portion thereof to promote adhesion. An advantage of adhesion to the housing wall is the ability to "seal" the composite structure to the housing without mechanical means. Such sealing (by whatever method) prevents the sample from channeling or bypassing the composite during operation. Preferably the structures of the present invention have a final bed height of from about 0.05 to about 5 mm. This allows for good washing, good density per unit volume, and results in a uniform precipitation during formation of the plug.

The Examiner believes this passage anticipates teaches the basic method steps contained in the instant claim 1 as well as the step of providing a plurality of porous

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particles. In example 9, equal pressure is maintained in a pipette while the polymeric matrix is formed. This meets the limitation of isobaric. Example 8 discloses a methanol/water quench mixture. Figures 5A-5D show a multiwell plate with polymeric structures cast in the wells.

Inventorship

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Kopaciewicz et al. (6,048,457) in view of Wheeler et al. (US 2003/0190260).

Kopaciewicz teaches every element of claim 5 except for the use of a quenching gas.

Kopaciewicz teaches the use of a liquid quencher. Kopaciewicz does teach air casting of the polymeric matrix though which requires an evaporation of the solvent used as the polymer binder (column 5, lines 20-58). Wheeler et al. (US 2003/0190260) teaches a combinatorial reactor system. The reactor system uses a quenching gas to stop reactions that are occurring in the reactors (page 9, paragraph 86). It would have been obvious to one of ordinary skill in the art to combine the quenching gas step of Wheeler with the method of Kopaciewicz. One would use a gas to quench the reaction to stop the reaction and help evaporate any solvent used in the casting.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure. Tubbs et al. (6,783,672) shows an affinity microcolumn contained in a housing. Husek (6,770,246) teaches a sorbent cartridge used in a pipette tip. Mehl


(4,774,058) teaches a support member having a porous disc attached to an open end. Avakian (3,985,032 and 4,059,020) shows a pipette tip with a filter on the end. Pascale et al. (4,902,421), Smith (5,364,595), and Puchinger et al. (4,999,164) display pipetting devices having porous materials in the tip.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
January 23, 2006


Jill Warden
Supervisory Patent Examiner
Technology Center 1700